

<div style="position: relative; height: 100px;"> <div style="position: absolute; top: 0; left: 0; width: 100%; height: 100%; background: repeating-linear-gradient(45deg, transparent, transparent 2px, black 2px, black 4px); border-radius: 50%; opacity: 0.5; z-index: 1;"></div> <div style="position: absolute; top: 0; left: 0; width: 100%; height: 100%; border: 2px solid black; border-radius: 50%; z-index: 2; display: flex; align-items: center; justify-content: center;"> <div style="text-align: center;"> <div style="font-size: 2em; font-weight: bold; margin-bottom: 5px;">O I P E</div> <div style="font-size: 1.2em; font-weight: bold;">SEP 20 2004</div> </div> </div> </div>				Complete if Known		
				Application Number		09/934,300
				Filing Date		8/21/01
				First Named Inventor		T. Talarico
				Group Art Unit		1645
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Examiner Name		S. Devi
Sheet	1	of	1	Attorney Docket Number		035780/233666
U. S. PATENT DOCUMENTS						
Examiner Initials*	Cite No.	Document Number Number - Kind Code (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document		Pages, Columns, Lines, Where Relevant Passages of Relevant Figures Appear
SD	15	US-5,234,903	08-10-1993	NHO <i>et al.</i>		
FOREIGN PATENT DOCUMENTS						
Examiner Initials	Cite No.	Foreign Patent Document Country Code - Number Kind Code (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	English Language Translation Attached
SD	16	WO 02/44214 A1	06-06-2002	Apex Bioscience, Inc.		
SD	17	WO 90/15613	12-27-1990	Rorer Int'l, Inc.		
OTHER DOCUMENTS						
Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.				English Language Translation Attached
SD	18	MATSUMURA, S., "Large Scale Production and Characterization of Lyophilized Pyridoxalated Hemoglobin-Polyoxyethylene (PHP)," <i>Biomat., Art. Cells & Immob. Biotech.</i> , 1992, Vol. 20(2-4), pp. 435-438.				
SD	19	TALARICO, T.L., "Comparability Analysis to Support a Manufacturing Site Change and Process Modifications for a Biopharmaceutical: A Regulatory Submission Case Study," <i>BioPharm</i> , 1999, Vol. 12(1), pp. 42-47.				
Examiner Signature	SD			Date Considered	November 04	

*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

RTA01/2162496v1

The PTO did not receive the following listed items(s) Cite # 16, 17, 18, 19